

R E M A R K S

Claims 1-8 are pending in the present application. The Applicants have amended the specification to correct typographical errors. The Applicants have also amended Claims 4 and 7 to include the term "composition" at the Examiner's suggestion. The Applicants have amended Claim 3 to better define their invention. Marked up versions of the amended paragraph and of the claims, showing all the changes relative to the previous version of the paragraphs and claims, are provided on separate pages at the end of this Response, in accordance with 37 CFR 1.121(b)(1)(iii) and 1.121(c)(1)(ii). For the Examiner's convenience, the Applicant's have provided a clean set of claims, as amended, following this Response after the pages with the marked up versions of the amended paragraph and claims.

The following objections and rejections are at issue and are set forth by number in the order they are herein addressed:

- 1) Claims 5-8 are rejected on the grounds that they are indefinite; because Claim 4 is subsequently specifically mentioned under this rejection, the Applicants assume that the Examiner meant to include Claim 4 in the rejection, and have responded accordingly;
- 2) Claims 1-8 are rejected under obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,015,833; and
- 3) Claims 1-8 are rejected under 35 U.S.C. §103, as allegedly obvious over Cook *et al.* (U.S. Pat. Nos. 5,554,646, "Cook 646") and Cook *et al.* (U.S. Pat. No. 5,428,072, "Cook 072") in view of Chin *et al.* (J Food Composition and Analysis 5: 185-197 (1992)).

Applicants believe the present amendments and following remarks traverse the Examiner's rejection of the Claims.

1. The Claims are Not Indefinite

Claims 5-8 (and presumably 4 as well) are rejected on the grounds that they are indefinite.

The Examiner objected to the term "a conjugated linoleic acid alkyl ester" in claims 4 and 7, asserting that the term means "a compound." The Applicants have amended Claims 4

and 7 so that they now read "a conjugated linoleic acid alkyl ester composition," as suggested by the Examiner.

The Examiner further objected to the term "low" in claim 7 as indefinite on the basis that it is not defined by either the claims or the specification. In contrast to the Examiner's assertion, the term "low" is defined in the specification as about 90 to 145 degrees C (see, for example, specification page 6, lines 26-27).

Because Claims 4 and 7 have been amended as described, and because the term "low" is defined in the specification, Claims 4-8 are not indefinite, and the Applicants respectfully request the withdrawal of the rejections of the claims as indefinite.

2. The Applicants will file a Terminal Disclaimer

Claims 1-8 are rejected under obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,015,833. The Applicants will file a terminal disclaimer upon notice of allowable subject matter.

3. The Claims are Not Obvious

Claims 1-8 are rejected under 35 U.S.C. §103, as allegedly obvious over Cook *et al.* (U.S. Pat. Nos. 5,554,646, "Cook 646") and Cook *et al.* (U.S. Pat. No. 5,428,072, "Cook 072") in view of Chin *et al.* (J Food Composition and Analysis 5: 185-197 (1992)). The Applicants respectfully traverse the Examiner's rejections on several grounds, including the Examiner's apparent misunderstanding of what the references teach, and of several legal standards.

The Examiner asserts that Cook '646 teaches an active form of conjugated linoleic acid, i.e., 10-12-octadecadienoic acid and 9,10-octadecadienoic acid, including ester, salt and free acid, and an animal feeding comprising such active form of the conjugated linoleic acid, but admits that the reference does not "teach expressly the conjugated linoleic acid active form further comprising the regio isomers 8,10- and an 11,13-octadecadienoic acid derivative" (Office Action, page 4). However, the Examiner asserts that because Chin *et al.* teaches that "it is known that c9,t11-conjugated linoleic acid isomer is a active form of conjugated linoleic acid," it would have been obvious "to make a conjugated linoleic ester mixture comprising predominantly c9,t11- and t10, c12-octadecadienoic ester without/or with less than 2% of

8,10- and 11,13-octadecadienoic ester" (Office Action, page 4, emphasis added). In fact, Chin *et al.* actually state, in the abstract, that the "c-9, t-11 CLA isomer is **believed** to be the biologically active form;" thus, the statement is simply a hypothesis which is repeated in the second paragraph of the introduction (see page 185). The Applicants also point out that a reference cited by the Examiner below, though not relied upon for an obviousness rejection, states "[t]o our knowledge, the identity of the biologically active CLA is not known" (Christie *et al.*). Finally, the Applicants point out that the combination of references relied upon by the Examiner for the obviousness rejection neither teaches the desirability of the low level of the undesirable isomers, nor how to obtain such a low level.

In response to the Applicants' arguments in the Preliminary Amendment, the Examiner asserts that "the cited prior art does not disclose the presence of any significant **amounts** of isomers such as the 8,10- and 11,13- isomer of conjugated linoleic acids in the compositions therein," and that purification of individual isomers of conjugated linoleic acid is "considered within the skill of artisan, absent the evidence to the contrary" (Office Action, page 5, emphasis added). But the Applicants did in fact present evidence to the contrary. The Applicants compared the results reported in a prior art reference, Sugano (submitted with the Response and Amendment dated March 28, 2000), with the results of Cook '646, because Sugano prepares CLAs by a method which is nearly identical to that used by Cook '646, and because Sugano DOES disclose the presence significant amounts of isomers such as the 8,10- and 11,13- isomer of conjugated linoleic acids in the compositions therein. The Applicants submit that the results reported by Sugano indicate that the amounts of the undesirable isomers in the compositions prepared by Cook would necessarily have to be about the same as though those reported by Sugano.

Comparison of the Sugano reference and the Cook patents reveals that Sugano prepared CLA from purified linoleic acid by a method similar to that utilized by Cook. In both methods, conjugation was performed in ethylene glycol at 180°C. The main differences are that the Cook patents utilize NaOH as the catalyst, as opposed to the KOH used by Sugano, and that the Cook patents heated the mixture for 2.5 hours, as opposed to the 2.0 hours used by Sugano. Sugano discloses that their CLA contained **18.6%** trans-trans isomers and **13.7%** other isomers, in addition to the c9,t11 and t10,c12 isomers. Applicants fail to understand how the Cook patents allegedly teach the "less than 2% of 8,10, 11,13 and trans-

trans isomers of CLA" element of the claims when it is clear that methods similar to those utilized by Cook result in a **much different composition**. Note that Cook heated the mixture for a longer period of time than did Sugano; it has been shown that longer reaction times at the same high temperature result in the production of even higher amounts of undesirable isomers (see, for example, US Patent No. 6,015,833, Example 3), suggesting that the amount of undesirable isomers present in the composition reported by Cook '646 would have been even higher than that reported by Sugano.

Moreover, the Applicants note that Cook '646 presented ABSOLUTELY NO QUANTITATIVE INFORMATION WHATSOEVER about the composition resulting from the reaction described. There is no analysis of the results, and no data describing the amounts of ANY conjugated linoleic acid present in the composition, much less WHAT conjugated linoleic acid is present. Therefore, it is incorrect to conclude that Cook '646 teaches less than 2% of 8,10, 11,13 and trans-trans isomers of CLA, when in fact the reference is silent as the amounts of ANY isomers present in the prepared composition. Further, the reference admits that undesirable isomers may be present (see column 5, lines 5-8), which underscores the fact that there is NO quantitative information about the amounts of different isomers present. The data reported by Sugano indicates that such undesirable isomers are in fact present.

The Examiner's response to the Applicants' arguments is that they are not persuasive, on the ground that every patent is presumed valid, citing MPEP 716.07. Patents are relevant as prior art for all that they contain, (MPEP 2123), which is not a question of validity. On other hand, a patent can't teach or suggest what it doesn't disclose. The Applicants are not arguing that the patent is or is not valid; instead, they are arguing that the reference Cook '646 does not teach the **amounts** of the 8,10 or 11,13 isomers present in their composition. Thus, Cook '646 can't teach or suggest the claimed invention directed to subject matter comprising specified **amounts** of the 8,10 and/or 11,13-isomers.

The Examiner complains that the data presented by the Applicants is insufficient and apparently incredible, asserting that the "data presented in the instant application lack the comparative chromatography data of 8,10 and 11,13 conjugated linoleic isomers and is not convincing that 8,10 and 11,13 conjugated linoleic isomers are not present in the compositions herein since the resolution of all these isomers is very poor (8,10 isomer is completely overlap with 9,11 isomer). See the chromatogram in Christie" (Office Action, page 6). The

Applicants cannot understand how the Examiner can question their quantitative data, and yet apparently have complete reliance upon Cook '646 and cite it against the Applicants, when Cook '646 presents ABSOLUTELY NO DATA WHATSOEVER about their composition, as pointed out above. Moreover, the information presented in a patent application is presumed to be credible absent sufficient evidence to the contrary (See, for example, *Fiers v. Revel*, 984 F.2d 1164, 1171-1172, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993)). Although the Examiner cites Christie as showing that the isomers can't be resolved, it's impossible to compare the results in the cited reference with those described by the Applicants, as the cited reference gives no information at all about the conditions under which the chromatography is performed. It is well known that chromatographic conditions greatly affect the separation of the compounds subjected to the chromatographic procedure. Furthermore, Christie concludes from his results that "most [commercial] samples of CLA [prepared by alkali-isomerization of linoleic acid or of oils]...also contain at least the 8,10 and 11,13 *cis, trans* dienes, sometimes at quite high levels." He then reports one commercial sample of CLA which contained 14 and 24 % of these isomers, respectively.

The Examiner has Not Established a *Prima Facie* Case of Obviousness

The Applicants repeat that the Examiner has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP § 2143). Failure to establish **any one** of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue. *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

A. The Combined References Do Not Teach Each Element of the Claims

The cited references do not teach each element of the claims. For example, neither primary reference, Cook '646 and Cook '072, teach or even suggest a composition

comprising conjugated alkyl esters comprising less than about two percent 8,10 and/or 11,13 octadecadienoic acid isomers. Nor is this deficiency remedied by the secondary reference, Chin *et al.* The Examiner's position appears to be that if a combination of references is silent about a claim element directed to subject comprising specified amounts of compounds which is less than about a certain amount, then the combination of the references is presumed to "teach or disclose" at least zero amounts of these compounds. Thus, the Examiner asserts "since the preferred amounts in the applicants claims are limited to less than 2 percent, this amount includes zero percent of the regio isomers. Thus, Cook' teachings met this limitation" (Office Action, page 4). This is incorrect. A combination of references which is ABSOLUTELY SILENT about a claim element does not either teach or suggest that claim element. The Applicants have presented evidence that the combination of references AT MOST describe a composition which would inherently have MUCH MORE than about two percent 8,10 and 11,13 octadecadienoic acid isomers.

Claims 1-6

Because the references cited by the Examiner do not teach or even suggest a composition comprising a specified low percentage of percent 8,10 and/or 11,13 octadecadienoic acid isomers, as is required by Claims 1-6, the Applicants respectfully request that the rejections of these claims be withdrawn.

Claim 2

The Examiner does not indicate that the references teach or even suggest a concentration of conjugated linoleic acid esters in animal feed of about 0.05 to 3.5% by weight, as is required by Claim 2. Therefore, Claim 2 is not obvious over the references cited by the Examiner, and the Applicants respectfully request that the rejection of this claim be withdrawn.

Claim 3

The Examiner does not indicate that the references teach or even suggest that the conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecanoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecanoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester, as is required by Claim 3. Therefore, this claim is not obvious over the references cited by the Examiner, and the Applicants respectfully request that the rejection of this claim be withdrawn.

Claims 4-6

The Examiner does not indicate that the references teach or even suggest a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, nor a composition further comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid, as is required by these claims. Therefore, these claims are not obvious over the references cited by the Examiner, and the Applicants respectfully request that the rejection of these claims be withdrawn.

Claims 7-8

The Examiner does not indicate that the cited references teach or even suggest a process which provides an unrefined linoleic acid alkyl ester having phosphatidyl residue in the range of about 0.1 to about 0.5 percent, nor one which causes isomerization of at least 50 percent of the linoleic acid alkyl ester to conjugated linoleic alkyl ester at low temperature, as is required by these claims. Moreover, these claims are not directed to subject matter comprising specified low levels of 8,10 and/or 11,13 octadecadienoic acid isomers, on which the Examiner's rejections are based. Therefore, these claims are not obvious over the references cited by the Examiner, and the Applicants respectfully request that the rejection of these claims be withdrawn

B. The Cited References do not Provide Reasonable Expectation of Success

The cited references do not provide a reasonable expectation of success for obtaining the claimed compositions.

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for making the claimed CLA composition. The Examiner states that "applicants have not demonstrated any unexpected results, e.g., in the purity of isomers useful herein over the prior art" (Office Action, page 5). Applicants respectfully submit that the above comparison of the Sugano reference and Cook patents presents ample evidence that Applicants achieved an unexpected result in producing CLA comprising less than 2% of 8,10, 11,13 and trans-trans isomers of CLA.

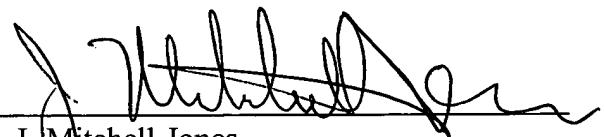
The Applicants further contend that the Cook patents provide absolutely no guidance or suggestion as to whether the 8,10 and 11,13 isomers of CLA should be minimized in the product and, indeed, how to actually minimize these isomers. As discussed above, the disclosure of the Cook patents is primarily directed to the 9,11 and 10,12 isomers of CLA. The existence of the other isomers is ignored. Therefore, Applicants submit that the Cook patents DO NOT provide a reasonable expectation of success in producing the claimed compositions when the Cook patents neither discuss the 8,10 and 11,13 isomers or provide methods for reducing their concentration in CLA compositions.

Accordingly, Applicants respectfully submit that the Examiner has not established a reasonable expectation of success for making the claimed invention. Therefore, Applicants request that the obviousness rejection be removed and the claims passed to allowance.

CONCLUSION

All grounds of rejection of the Office Action of June 21, 2000 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call Mitchell Jones collect at (608) 218-6900.

Dated: March 28, 2001


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

in accordance with 37 CFR 1.121(b)(1)(iii)

IN THE SPECIFICATION:

The paragraph starting on line 13 of page 8 has been amended as follows:

Applicants have discovered that if sunflower or safflower oil is utilized, the resulting phosphatidyl and sterol residues are low enough for the material to be characterized as food grade. In particular, Applicants first provide the sunflower or safflower oil as delivered by tanker, subject it to fat [slitting] splitting and esterification, and then proceed directly with the unrefined esterification product into isomerization. The usual purification and refining steps are not necessary. This material can be made in commercial scale quantities at a low enough cost to be practical as a feed or food supplement.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

in accordance with 37 CFR 1.121(c)(1)(ii)

IN THE CLAIMS:

Claims 3, 4 and 7 have been amended as follows:

3. (Amended once) The animal feed of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecanoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecanoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester, with less than [5] about two percent of 11,13-octadecanoic acid alkyl ester.

4. (Amended twice) A conjugated linoleic acid alkyl ester composition for safe use as a feed, food ingredient, or food supplement obtained by direct isomerization of an unrefined linoleic acid comprising

a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, and combinations thereof, and

in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and

in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.

7. (Amended once) A conjugated linoleic acid alkyl ester composition for use in domestic animal feed, food ingredients, or human dietary supplements made by the process comprising

providing an unrefined linoleic acid alkyl ester having phosphatidyl residue in the range of about 0.1 to about 0.5 percent

treating with an alkali alcoholate at low temperature in the presence of a monohydric low molecular weight alcohol to cause isomerization of at least 50 percent of the linoleic acid alkyl ester to conjugated linoleic alkyl ester at low temperature,

acidifying by addition of an aqueous acid, and

separating the linoleic conjugated linoleic acid alkyl ester from said aqueous acid without distillation.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Saebo *et al.*

Serial No.: 09/132,593

Group No.: 1615

Filed: 08/11/98

Examiner: D. Faulkner

Entitled:

**CONJUGATED LINOLEIC ACID ALKYL ESTERS IN FEED
STUFFS AND FOOD**

COURTESY COPY FOR EXAMINER'S CONVENIENCE ONLY

CLEAN SET OF PENDING CLAIMS

(in Amendment and Response filed 03/28/01 in response to Office Action 11/28/2000)

1. (Amended once) An animal feed comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent 8,10 and 11,13 octadecadienoic acid isomers.
2. The animal feed of claim 1 wherein the concentration of conjugated linoleic acid alkyl esters in said feed is about 0.05 to 3.5 percent by weight.
3. (Amended once) The animal feed of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecanoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecanoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester, with less than [5] about two percent of 11,13-octadecanoic acid alkyl ester.
4. (Amended twice) A conjugated linoleic acid alkyl ester composition for safe use as a feed, food ingredient, or food supplement obtained by direct isomerization of an unrefined linoleic acid comprising
 - a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, and combinations thereof, and
 - in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and

in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.

5. The ester of claim 4 wherein said c9,t11-octadecanoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecanoic acid alkyl esters.

6. The ester of claim 4 wherein said t10,c12-octadecanoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecanoic acid alkyl esters.

7. (Amended once) A conjugated linoleic acid alkyl ester composition for use in domestic animal feed, food ingredients, or human dietary supplements made by the process comprising

providing an unrefined linoleic acid alkyl ester having phosphatidyl residue in the range of about 0.1 to about 0.5 percent

treating with an alkali alcoholate at low temperature in the presence of a monohydric low molecular weight alcohol to cause isomerization of at least 50 percent of the linoleic acid alkyl ester to conjugated linoleic alkyl ester at low temperature,

acidifying by addition of an aqueous acid, and

separating the linoleic conjugated linoleic acid alkyl ester from said aqueous acid without distillation.

8. The ester of claims 1-7 wherein said alkyl ester has an alkyl radical selected from the group consisting of methyl-, ethyl-, propyl-, isopropyl-, butyl-, and isobutyl-.